ENTERAL NUTRITIONAL HYPOALLERGENIC FORMULA

This is a continuation-in-part of U.S. patent application Ser. No. 695,993 filed on Jan. 29, 1985 now abandoned.

FIELD OF THE INVENTION

The invention relates to improved enteral nutritional hypoallergenic formulas and more particularly to hypoallergenic formulas which contain a unique fat emulsifying system.

BACKGROUND OF THE INVENTION

Hypoallergenic formulas or compositions, which are also referred to as elemental formulas, are characterized in that they contain protein hydrolysates such as soy protein hydrolysate, casein hydrolysate, whey protein hydrolysate or a combination of animal and vegetable protein hydrolysates as a major source of nitrogen. The protein hydrolysates comprise short peptide fragments and/or free amino acids instead of the intact protein found, for example, in cow's milk and soy protein isolate-based formulas. These short peptide fragments and free amino acids have been found to be less immunogenic or allergenic than intact proteins.

In addition to protein hydrolysates, most nutritionally balanced hypoallergenic formulas contain carbohydrates, lipids, vitamins, minerals and are supplemented with additional amino acids to upgrade the nutritional quality of such formulas. These hypoallergenic formulas are utilized for feeding infants, children and adults who have allergies or sensitivities to intact protein, and are often medically used in the treatment of cystic fibrosis, chronic diarrhea, galactosemia, small bowel resection, steatorrhae and protein-calorie malnutrition.

One well known problem in the preparation of hypoallergenic formulas is that extensive protein hydrolysis by acids or enzymes is necessary to provide the short peptides and amino acids utilized in the formulas to render such formulas hypoimmunogenic. These extensively digested and hypoimmunogenic protein hydrolysates have the undesirable characteristic of loss of capacity to emulsify fat and form physically stable emulsions that do not separate during storage.

Another common problem encountered in the preparation of hypoallergenic formulas is the formation of undesirable brown color as a result of the reaction between the carbonyl groups of reducing sugars and the nitrogen-amine-containing compounds such as amino acids in the formula (Maillard type reaction), especially at elevated temperatures encountered during sterilization. In addition to the brown color formation, Maillard type reaction also results in loss of the nutritional value of the protein hydrolysate.

U.S. Pat. No. 4,414,238 shows an elemental diet composition comprising carbohydrates, amino acids and/or low molecular weight peptides and lipids. The elemental diet of that patent has a lipid component in the form of an emulsion consisting of lipids, an emulifier selected from the group consisting of mono- and diglycerides, and a corn starch modified with succinic anhydride and is stable and non-browning at a low pH of about 3 to 4.4.

The present invention provides an improved hypoallergenic formula which does not require emulsifiers such as mono- or diglycerides, does not form a brown color at a higher pH range than previous hypoallergenic formulas, and is a stable emulsion. Furthermore, the hypoallergenic formula of the present invention enables suspension of the insoluble calcium and phosphorus salts which are commonly contained in such formulas.

SUMMARY OF THE INVENTION

The present invention is an improved hypoallergenic formula comprising carbohydrates, lipids, a protein hydrolysate, vitamins and minerals and a starch modified by octenyl succinic anhydride which is the sole emulsifying agent. The invention is based on the discovery that the lipophilic moiety of the modified starch of the present invention results in a stable emulsion which is non-browning at a higher pH than previous hypoallergenic formulas.

DETAILED DESCRIPTION OF THE INVENTION

The hypoallergenic formula of the invention is made by blending carbohydrates, lipids, and a protein hydrolysate, homogenizing the mixture into a stable emulsion and sterilizing the product in the pH range from about 6 to about 7.

The protein hydrolysate of the invention may be any suitable protein hydrolysate utilized in a nutritional formula such as soy protein hydrolysate, casein hydrolysate, whey protein hydrolysate, animal and vegetable protein hydrolysates, and mixtures thereof. The protein hydrolysate of the hypoallergenic formula of the invention is preferably a soy protein hydrolysate or a casein hydrolysate comprising short peptides and amino acids. The immunogencity of the formula of the present invention depends largely on the extent of hydrolysis of the selected protein hydrolysate. To insure hypoimmunogenicity of the formula, the protein hydrolysate should be extensively hydrolyzed to yield very short peptides and free amino acids. This is important since free amino acids and di- and tripeptides are known to be absorbed through the small intestine without any digestive breakdown. Large molecular weight peptides are preferably avoided because they generate a more antigenic formula and cause precipitation and emulsion destabilization. In a preferred embodiment, the protein hydrolysate of the invention contains a high percentage of low molecular weight peptide fragments.

Preferably, the protein hydrolysate of the present invention is hydrolyzed to such an extent that the ratio of the amino nitrogen (A.N.) to total nitrogen (T.N.) ranges from about 0.4 A.N. to 1.0 T.N. to about 0.7 A.N. to 1.0 T.N. Such extent of hydrolysis generally yields protein hydrolysate with the following molecular weight distribution:

Molecular Weight (Daltons)	Percent in Hydrolysate
<500	77–95
500–1500	3–12
1500–5000	1–7
>5000	<3

The hydrolyzed protein source of the hypoallergenic formula is also preferably supplemented with various free amino acids to provide a nutritionally balanced amino acid content. Examples of such free amino acids include L-tryptophan, L-methionine, L-cystine, L-tyrosine, L-arginine, taurine and carnitine. The amount of protein hydrolysate and supplemented free amino acid